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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,461	10/15/1999	OMAR S. KHALIL	6351.US.P2	1303

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EXAMINER	
KREMER, MATTHEW J	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 09/29/2004

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/419,461	KHALIL ET AL.	
	Examiner	Art Unit	
	Matthew J Kremer	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8-12,15-20,26-30,33-38,44-47 and 49-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8-12,15-20,26-30,33-38,44-47 and 49-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2/2004;7/5/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/2/2004 has been entered.

Information Disclosure Statement

2. Applicant has requested an initialed copy of an Information Disclosure Statement (IDS) filed on 2/2/2004, which is identical to the IDS filed on 7/5/2002, because the copy of the IDS filed on 7/5/2002 was not received. The 2/2/2004 IDS was not initialed since those references were already considered in the 7/5/2002 IDS. Both the 2/2/2004 IDS and 7/5/2002 IDS accompany this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 53 recites the limitation "wherein the distance between (a) the source of light for irradiating a region of said biological sample with light and (b) the means for collecting light re-emitted from said region of said biological sample is less than two millimeters". The Applicant cites pages 33-34 of the specification for support for this claim. The Examiner respectfully disagrees. The specification provides a teaching that the distance can be between 0.44 to 1.84 mm but does not support a teaching that the distance can be between 0 to 2 mm. Therefore, any claim reciting a distance outside the disclosed range of 0.44 to 1.84 mm is not supported by the specification and is considered to improperly include new matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-2, 8-12, 15-20, 26-30, 33-38, 44-47, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of *ex vivo* human dermis and subdermis" by Laufer et al. (Laufer)(cited by Applicant) in view of U.S. Patent 5,497,769 to Gratton et al. (Gratton). Mills discloses a method and apparatus for monitoring blood parameters which makes use of measurements of the behavior of substances which are affected by temperature. (column 1, lines 16-25 of Mills). Mills teaches that to generate data, the temperature induction means is used to bring the finger (or tubing or other space of interest) to a known temperature, light of known wavelength and intensity is emitted on the surface of interest. (column 9, lines 1-33 of Mills). Detection of the light signal at a distinct point (normally opposing surface) is made and the relative absorbance and extinction of the signal is calculated. The process is repeated at the next chosen wavelength, while still at the same predetermined temperature. Once the desired number of wavelengths has been examined, the temperature induction means would bring the volume to a predetermined second temperature, and the data collection of steps would be repeated. At the completion of measurements and determinations for this second temperature, the temperature induction means will bring the space to a third predetermined temperature, and the measurements and determinations repeated. This process would be continued until the desired range of temperatures has been sampled. Mills does not explicitly disclose that the first temperature corresponds to a first depth in the body part and the second temperature corresponds to a second depth in the body part. Laufer presents a

study on the influence of temperature on the optical properties of human dermis and subdermis. Laufer discloses that there is a decrease in the scattering coefficient for the subdermis and an increase for the dermis with temperature. (page 2488 of Laufer). This implies that at different temperatures, different layers are being measured in relation to reflected measurements since the average sampling depth of the measurements is shifting. Functionally, the method of Mills performs this operation since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Mills to include the fact that a temperature corresponds to the depth in a body part as disclosed by Laufer since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. The combination does not teach that the optical measurement is a spatially resolved diffuse reflectance measurement but the combination does teach the use of reflectance measurements (column 8, lines 1-3 of Mills) and the device can be used at a variety of places. (column 7, lines 55-59 of Mills). Gratton teaches a spatially resolved diffuse reflectance measurement (Figs. 1-2 of Gratton) that determines scattering and absorption coefficients (column 3, lines 36-38 of Gratton) that providing reflectance measurements without the need to pass light through a narrow portion of tissue so that a more central area of the body can be used (column 2, lines 35-39 of Gratton). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify combination to include spatially resolved reflectance as disclosed by Gratton since Gratton provides

reflectance measurements without the need to pass light through a narrow portion of tissue so that a more central area of the body can be used. In regard to claims 8 and 26, Mills teaches that temperature of interest include 33 to 40 degree Celsius (column 13, lines 15-25 of Mills). In regard to claims 9-10, 27-28, and 44-45, Mills indicates that 660 and 940 nm are wavelengths of interest in oximetry in which these procedures can be used. (Fig. 11 of Mills). In regard to claims 11-12, 29-30, and 46-47, Mills teaches that glucose and hemoglobin can be measured. (column 13, lines 31-35 of Mills). In regard to claims 15-16, 33-34, and 49, Mills performs experiments on the finger. (Fig. 6 of Mills). In regard to claims 17-18, 35-36, and 50-51, Mills states that the invention can be used to determine sickle cell disease, certain cancers, and other diseases or conditions which are distinguished by markers in blood. (column 14, lines 11-25 of Mills).

7. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of *ex vivo* human dermis and subdermis" by Laufer et al. (Laufer)(cited by Applicant) in view of U.S. Patent 5,497,769 to Gratton et al. (Gratton) as applied to claim 37, and further in view of U.S. Patent 5,873,821 to Chance et al. (Chance '821). The combination does not teach the use of an endoscope. Chance '821 teaches that the oximeter can be disposed on an endoscope, catheter or guidewire or the like for examination of internal tissue. (column 6, lines 48-54 of Chance '821). Therefore, it would have been obvious to one having ordinary skill in the art at the time

the invention was made to modify combination to include an endoscope as disclosed by Chance '821 since an endoscope would allow examination of internal tissue.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 8, 9-12, 15-16, 19, 26-28, 29-30, 33-34, 37-38, 44-47, 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 40, and 42-43 of U.S. Patent No. 6,662,030 to Khalil et al. (Khalil) in view of the journal publication "Effect of temperature on the optical properties of *ex vivo* human dermis and subdermis" by Laufer et al. (Laufer)(cited by Applicant), and further in view of U.S. Patent 5,497,769 to Gratton et al. (Gratton). Claim 13 of Khalil discloses a method of measuring one or more parameters of a body part by setting the body to one temperature (step a of claim 13), taking an optical measurement of light which has been reflected, scattered, absorbed, or emitted (step b of claim 13), determining an optical property (step c of claim 13), setting the body to another

temperature (step d of claim 13), determining an optical property (step e of claim 13), and analyzing the optical properties to determine one parameter (step f of claim 13). Khalil does not claim that the first temperature corresponds to a first depth in the body part and the second temperature corresponds to a second depth in the body part. Laufer discloses on page 2488 that there is a decrease in the scattering coefficient for the subdermis and an increase for the dermis with temperature. It is implied that at different temperatures, different layers are being measured in relation to reflected measurements since the average sampling depth of the measurements is shifting. Functionally, the method of Khalil performs this operation since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Khalil to include the fact that a temperature corresponds to the depth in a body part as disclosed by Laufer since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Claim 13 of Khalil claims the optical property is reflectance. Gratton teaches a spatially resolved diffuse reflectance measurement (Figs. 1-2 of Gratton) that determines scattering and absorption coefficients (column 3, lines 36-38 of Gratton) that providing reflectance measurements without the need to pass light through a narrow portion of tissue so that a more central area of the body can be used (column 2, lines 35-39 of Gratton). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify combination to include spatially resolved reflectance as disclosed by Gratton since

Gratton provides reflectance measurements without the need to pass light through a narrow portion of tissue so that a more central area of the body can be used. Claims 1, 11-12, 19, and 29-30 are rejected over the combination, which includes claim 13 of Khalil. In regard to claims 8 and 26, Khalil claims the use of different temperatures and Laufer teaches four different suitable temperatures: 25, 30, 35, and 40°C (page 2479 of Laufer). In regard to claims 9-10 and 27-28, Khalil claims the use of wavelengths and Laufer teaches suitable wavelengths between 650 and 1000 nm. (Figs. 2-3 of Laufer). In regard to claims 15-16 and 33-34, claim 13 claims a body part is examined and Gratton teaches that the skin is suitable body part. (Figs. 1 of Grattton).

In regard to claims 37-38 and 46-47, claim 40 of Khalil claims a source of light (element (c) of claim 40), a means for collecting (element (b) of claim 40), a means for changing the temperature (element (a) of claim 40), a detector (element (c) of claim 40), and a means for calculating (element (d) of claim 40). Khalil does not claim that the first temperature corresponds to a first depth in the body part and the second temperature corresponds to a second depth in the body part. Laufer discloses on page 2488 that there is a decrease in the scattering coefficient for the subdermis and an increase for the dermis with temperature. It is implied that at different temperatures, different layers are being measured in relation to reflected measurements since the average sampling depth of the measurements is shifting. Functionally, the method of Khalil performs this operation since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the method of Khalil to include the fact that a temperature corresponds to the depth in a body part as disclosed by Laufer since the fact that the average sampling depth in a tissue changes with temperature is a naturally occurring phenomenon. Claim 40 of Khalil claims an optical property is determined from reflected light, i.e., a reflectance measurement. Gratton teaches a spatially resolved diffuse reflectance measurement (Figs. 1-2 of Gratton) that determines scattering and absorption coefficients (column 3, lines 36-38 of Gratton) that fulfills the requirements of providing reflectance measurements as set forth in the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify combination to include spatially resolved reflectance as disclosed by Gratton since claim 40 of Khalil claims the use of reflectance measurements and Gratton teaches such measurement. In regard to claim 49, claim 40 claims a body part is examined and Gratton teaches that the skin is suitable body part. (Figs. 1 of Grattton).

In regard to claim 44, claim 42 of Khalil claims the necessary wavelength ranges.

In regard to claim 45, claim 43 of Khalil claims the necessary wavelength ranges.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 8-12, 15-20, 26-30, 33-38, 44-47, and 49-53 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ERIC F. WINAKUR
PRIMARY EXAMINER